K090607

APR 22 2009

5. 510(k) Summary

Trade Name:	Blue Sky Plan
Common Name:	3D Dental Image Processing Software
Classification Name:	Picture archiving and communications system -21 CFR 870.2050. This device is categorized as LLZ and is regulated as Class II.
Submitter Information:	Blue Sky Bio, LLC 888 E. Belvidere Rd., Suite 212 Grayslake, IL 60030 USA Tel: 718.376.0422; Toll Free Tel: 888.446.6724 Fax: 888.234.3685
Summary Prepared By:	Albert Zickmann, DDS President
Date Prepared:	February 26, 2009
Predicate Devices:	Virtual Implant Placements (VIP), K060267 Accurex, K061126

Device Description:
Blue Sky Plan™ is dental imaging software which loads DICOM images and provides 3D visualization, 2D image reformation for surgical implant planning and stent fabrication, which allows the virtual position of implants from the images supplied by computerized tomography.

Indications for Use:
Blue Sky Plan is intended to be used as conversion software for Computed Tomography (CT) generated DICOM images into a format that allows a dentist to assess the anatomic topography of the maxilla and mandible as well as location of important structures. It allows the information to be used for pre-surgical treatment planning of dental implant procedures. The Blue Sky Plan software is deployed on standard personal computer hardware using a Windows operating system.

Technological Characteristics:
The technological characteristics of the new device are compatible to those of the predicate devices.

Conclusions:
The indications for use are consistent with the previously indicated predicate devices and in the applicable FDA classification regulation. Differences in technological characteristics from those of the cited predicate devices do not raise new issues of safety or effectiveness and are addressed in the submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2009

Dr. Albert Zickmann
President
Blue Sky Bio, LLC
888 E. Belvidere Road, Suite 212
GRAYSLAKE IL 60030

Re: K090607
Trade/Device Name: Blue Sky Plan
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 3, 2009
Received: March 6, 2009

Dear Dr. Zickmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K090607

Device Name: Blue Sky Plan

Indications for Use:

Blue Sky Plan is intended to be used as conversion software for Computed Tomography (CT) generated DICOM images into a format that allows a dentist to assess the anatomic topography of the maxilla and mandible as well as location of important structures. It allows the information to be used for pre-surgical treatment planning of dental implant procedures. The Blue Sky Plan software is deployed on standard personal computer hardware using a Windows operating system.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090607